DEPARTMENT OF HEALTH & HUMAN SERVICES

Food and Drug Administration
Rockville MD 20857

JUN 5 2012

Re: PROGEL PLEURAL AIR LEAK SEALANT
Docket No.: FDA-2010-E-0399

The Honorable David J. Kappos
Undersecretary of Commerce for Intellectual Property
Director of the United States Patent and Trademark Office
Mail Stop Hatch-Waxman PTE
P.O. Box 1450
Alexandria, VA 22313-1450

Dear Director Kappos:

This is in regard to the application for patent term extension for U.S. Patent No. RE38158, filed by Neomend, Inc., under 35 U.S.C. section 156 et seq. We have reviewed the dates contained in the application and have determined the regulatory review period for PROGEL PLEURAL AIR LEAK SEALANT, the medical device claimed by the patent.

The total length of the regulatory review period for PROGEL PLEURAL AIR LEAK SEALANT is 3,854 days. Of this time, 787 days occurred during the testing phase and 3,067 days occurred during the approval phase. These periods of time were derived from the following dates:

1. The date an exemption under section 520(g) of the Federal Food, Drug, and Cosmetic Act involving this device became effective: June 29, 1999.

   FDA has verified the applicant's claim that the date the investigational device exemption (IDE) required under section 520(g) of the Federal Food, Drug, and Cosmetic Act for human tests to begin became effective on June 29, 1999.

2. The date the application was initially submitted with respect to the device under section 515 of the Federal Food, Drug, and Cosmetic Act: August 23, 2001.

   FDA has verified the applicant's claim that the premarket approval application (PMA) for PROGEL PLEURAL AIR LEAK SEALANT (PMA P010047) was initially submitted on August 23, 2001.

3. The date the application was approved: January 14, 2010.

   FDA has verified the applicant's claim that PMA P010047 was approved on January 14, 2010.

This determination of the regulatory review period by FDA does not take into account the effective date of the patent, nor does it exclude one-half of the testing phase as required by 35 U.S.C. section 156(c)(2).

Please let me know if we can be of further assistance.

Sincerely yours,

Jane A. Axelrad

Jane A. Axelrad
Associate Director for Policy
Center for Drug Evaluation and Research

cc: N. Nicole Endejann/ Raymond A. Miller
Pepper Hamilton LLP
500 Grant Street
Pittsburgh, PA 15219